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ABSTRACT

Recognizing the need for a formal process on oversight and protection of human subjects in the research process, Nova Southeastern University established an Institutional Review Board Task Force in May 1996. The Institutional Review Board (IRB) was evaluated in this study by those with operational knowledge of its activities: committee members and principal investigators who have engaged with the IRB in the last few years. An iterative process was used to develop the survey instrument, which was sent to 149 committee members and principal investigators. Responses were received from 20 participants (13.4%), and there is concern about how representative the respondents are of the population as a whole. Overall, survey respondents were quite positive in their judgment of the University's IRB. Nearly 96% of statements about the IRB in the survey received a modal rating of 4 ("agree") or 5 ("Strongly Agree"). The only statement to receive a modal rating of three was about feedback from the center representative. Participants were especially positive on their level of satisfaction with service and support provided by staff in the University's Office of Grants and Contracts. The findings serve as an additional demonstration to external constituencies of the University's commitment to the continuous nature of internal assessments that address the spirit of the institutional effectiveness process. The survey is attached. (SLD)

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FACULTY AND STUDENTS AT NOVA SOUTHEASTERN UNIVERSITY JUDGE THE INSTITUTIONAL REVIEW BOARD (IRB) FOR RESEARCH WITH HUMAN SUBJECTS: FALL TERM 2001

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Nova Southeastern University
Research and Planning

Report 01-16

November 2001

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FACULTY AND STUDENTS AT NOVA SOUTHEASTERN UNIVERSITY JUDGE THE INSTITUTIONAL REVIEW BOARD (IRB) FOR RESEARCH WITH HUMAN SUBJECTS: FALL TERM 2001

Thomas W. MacFarland **Senior Research Associate**
Report 01-16 **November 2001**

EXECUTIVE SUMMARY

The protection of human subjects in university-sponsored research has received the highest level of attention from the United States government. Policy has been established and violations have resulted in the temporary suspension of human-subject research at institutions as diverse as Duke University, Virginia Commonwealth University, and Johns Hopkins University.

Recognizing the need for a formal process on oversight and protection of human subjects in the research process, Nova Southeastern University established an Institutional Review Board Task Force in May 1996. Based on recommendations from the task force, the University established a formal Institutional Review Board (IRB) for Research with Human Subjects, which has been operational for approximately five years. Committee membership on the Institutional Review Board is widely representative of the University community.

The purpose of this report is to offer an assessment of the Institutional Review Board by those with operational knowledge of its activities: committee members and principal investigators who have engaged with the Institutional Review Board in the last few years. This report represents the first formal assessment of the University's Institutional Review Board.

An iterative process was used to develop the survey instrument associated with this report, with leadership for survey development coming from an *Ex-Officio* member of the Institutional Review Board (IRB) and the Assistant to the President for Academic Affairs. The population consisted of all current Institutional Review Board (IRB) committee members (N = 22) and faculty and students who, as principal investigators, submitted research protocols to the Institutional Review Board for full or expedited review in 1999, 2000, and 2001 (N = 129). There were two committee members who were also included among the list of principal investigators, resulting in an unduplicated N = 149. As part of the mandate for participation in the IRB process by a broadly inclusive array of University associates, it is useful to note that the population included at least one member from each academic center and college at the University.

Surveys were distributed by the Office of Grants and Contracts and returned to the Office of Research and Planning, with a suggested survey return deadline of September 28, 2001. Surveys

were returned by 20 participants from a population of 149 members, resulting in a survey return of 13.4 percent. The response rate was clearly less than desired and there is a concern about the unknown representation of the responding sample in terms of the population.

Overall, survey respondents were quite positive regarding their judgment of the University's Institutional Review Board, as evidenced by responses to the 24 statements on the survey asking for quantitative assessment:

- Nearly 96 percent (23 of 24) of all statements received a modal rating of either 4 (Agree) or 5 (Strongly Agree). The only statement to receive a modal rating of 3 was specific to judgment on feedback from the center representative.
- The lowest mean rating (Mean = 3.50 and SD = 0.8) was specific to judgment on the IRB Manual.
- Participants were especially positive on their level of satisfaction with service and support provided by staff in the Office of Grants and Contracts. All six statements on this part of the survey received a modal rating of 5 (Strongly Agree) and a mean rating of 4.50 or greater.

Of course, this report and the results coming from this report need to be viewed in context of the low survey return percentage, which was less than 15 percent. It is unknown if survey results are representative of the population and this concern is a limitation on the efficacy of this report. In future iterations of this survey process, some communication mechanism needs to be considered to increase the rate of survey return by invited participants.

Along with possible reaction to actual survey results, this report is also useful in that it serves as an additional demonstration to external constituencies of the University's commitment to the continuous nature of internal assessments that address the spirit of the Institutional Effectiveness process. This internal assessment process is pervasive to the entire fabric of the University and it is implemented to continually strive for improvement in how the University meets its stated goals.

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BACKGROUND

Introduction

The protection of human subjects in university-sponsored research has received considerable attention in recent years. The United States government has established policy on the protection of human subjects (http://www.ed.gov/offices/OCFO/humansub/overview.html) and government concern about insufficient university oversight of the research process has caused temporary suspension of human-subject research at institutions as diverse as Duke University (Brainard, 2000a), Virginia Commonwealth University (Brainard, 2000b), and Johns Hopkins University (Curry, 2001).

Recognizing the need for a formal process on oversight and protection of human subjects in the research process, Nova Southeastern University established an Institutional Review Board Task Force in May 1996. Based on recommendations from the task force, the University established a formal Institutional Review Board (IRB) for Research with Human Subjects.

Purpose of This Report

The University's Institutional Review Board (IRB) for Research with Human Subjects has been operational for approximately five years. Committee membership is widely representative of the University community and all relevant documents are made available on a public Web page, at http://www.nova.edu/cwis/ogc/irb. The purpose of this report is to offer an assessment of its operations by those with operational knowledge of its activities: committee members and principal investigators who have engaged with the Institutional Review Board in the last few years. This report represents the first formal assessment of the University's Institutional Review Board.

METHODOLOGY

Survey Development

The University's Office of Research and Planning was approached in mid-August 2001 by an *Ex-Officio* member of the Institutional Review Board (IRB) and the Assistant to the President for Academic Affairs, requesting assistance with survey development and methodology regarding an assessment of the IRB. From this initial request, an iterative process that included IRB

committee members was used to prepare a draft survey that focused on the University's Institutional Review Board. The draft survey was further reviewed by University personnel and it was put into final form by early-September 2001. A copy of the survey is appended to this report.

Population and Sample

The population consisted of all current Institutional Review Board (IRB) committee members (N = 22) and faculty and students who, as principal investigators, submitted research protocols to the Institutional Review Board for full or expedited review in 1999, 2000, and 2001 (N = 129). There were two committee members who were also included among the list of principal investigators, resulting in an unduplicated N = 149. As part of the mandate for participation in the IRB process by a broadly inclusive array of University associates, it is useful to note that the population included at least one member from each academic center and college at the University.

As the population was identified, University employees were not identified by specific job status and it is only possible to provide subtotal information for this identifier. As presented in Table 1, the population consisted of University employees (N = 80, 53.7 percent), students (N = 67, 45.0 percent) and community members (N = 2, 1.3 percent). Academic center affiliations of the population are presented in Table 2. As part of the mandate for participation in the IRB process by a broadly inclusive array of University associates, it is useful to note that the population included at least one member from each academic center and college at the University.

Surveys were distributed by the Office of Grants and Contracts and returned to the Office of Research and Planning, with a suggested survey return deadline of September 28, 2001. Surveys were returned by 20 participants from a population of 149 members, resulting in a survey return of 13.4 percent. Characteristics of survey respondents are provided in Table 1 and Table 2. It should be noted that the response rate was clearly less than desired and there is always a concern that the responding sample may not be representative of the population.

RESULTS

A set of tables (Table 3 to Table 8) provide descriptive statistics on survey results, providing breakout information by:

Table 3 IRB Web Site

Table 4 Policy and Procedure Manual for Research with Human Subjects

Table 5 IRB Forms

Table 6 IRB Service and Support

Table 7 Center/College Representative

Table 8 Institutional Review Board

Overall, survey respondents were quite positive regarding their judgment of the University's Institutional Review Board, as evidenced by responses to the 24 statements on the survey asking for quantitative assessment:

- Nearly 96 percent (23 of 24) of all statements received a modal rating of either 4 (Agree) or 5 (Strongly Agree). The only statement to receive a modal rating of 3 was specific to judgment on feedback from the center representative (Table 7).
- The lowest mean rating (Mean = 3.50 and SD = 0.85) was specific to judgment on the IRB Manual (http://www.nova.edu/cwis/ogc/irb/manual.html).
- Participants were especially positive on their level of satisfaction with service and support provided by staff in the Office of Grants and Contracts. All six statements on this part of the survey received a modal rating of 5 (Strongly Agree) and a mean rating of 4.50 or greater.

Although survey results were generally positive, there is obviously some level of concern that the survey return rate was less than 15 percent and it is unknown if results from this survey process are representative of the population. This concern is especially evident in that all members of the population have had some level of engagement with the University Institutional Review Board and the processes established by this board. As this survey process is replicated in the future, some additional level of communication will be needed to encourage greater participation in this assessment activity.

SUMMARY

The United States government has established strict standards designed to protect human subjects engaged in University-sponsored research activities. This level of protection is so encompassing that there are now procedures that compel University personnel to participate in formal inservice training activities when involved in research with human subjects, as evidenced by the following policy statement:

REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

Release Date: June 5, 2000 (Revised August 25, 2000)

NOTICE: OD-00-039

National Institutes of Health

Policy: Beginning on October 1, 2000, the NIH will require education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects.

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html

Regarding this mandate for education on the protection of human subjects, the Office of Human Research Protections (OHRP) includes a tutorial for the Institutional Official, the IRB Chair and the Primary Contact as well as IRB members in the following three areas:

- Federal Regulations and Institutional Responsibilities
- Investigator Responsibilities and Informed Consent
- Human Protections Program Administration and IRB Responsibilities

After full implementation of the Institutional Review Board, a number of training sessions were conducted for faculty on the IRB process. Periodically, the IRB chair has conducted training for IRB members and interested faculty. Furthermore, the Director of the Office of Grants and Contracts included the topic of IRB in any workshops conducted for faculty and students. Moreover, a videotape of an IRB presentation is available for faculty.

The University uses mechanisms established by the Institutional Review Board to meet the spirit and the letter of accepted research practice with human subjects. This report is a summary of judgment of the University's Institutional Review Board, encompassing feedback from committee members and participants who have served in the last few years in the role of principal investigator on those research protocols requiring expedited or full review by the Institutional Review Board.

There was a high level of satisfaction with the University's Institutional Review Board and all statements received positive ratings (Mean > 3.0 on a 1 = Strongly Disagree to 5 = Strongly Agree Likert-type rating scale). Survey statements about satisfaction with services provided by staff in the Office of Grants and Contracts received the highest overall ratings.

Of course, this report needs to be viewed in context of the low survey return percentage, which was less than 15 percent. It is unknown if survey results are representative of the population and this concern is a limitation on the efficacy of this report. In future iterations of this survey process, some communication mechanism needs to be considered to increase the rate of survey return by invited participants.

Along with possible reaction to actual survey results, this report is useful in that it serves as an additional demonstration to external constituencies of the University's commitment to the continuous nature of internal assessments that address the spirit of the Institutional Effectiveness process. This internal assessment process is pervasive to the entire fabric of the University and it is implemented to continually strive for improvement in how the University meets its stated goals.

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United States Department of Education. (April 2, 2001). *Information About the Protection of Human Subjects in Research Supported by the Department of Education - Overview*. <http://www.ed.gov/offices/OCFO/humansub/overview.html>. Accessed October 31, 2001.

Table 1

Employment Status or Student Status: Population and Survey Respondents

Status	Population		Respondents	
	N	% Total	N	% Total
Dean or associate/assistant dean			0	0.0
Academic department chairperson/director			3	15.0
Faculty member			10	50.0
Employee subtotal[1]	80	53.7	13	65.0
Student	67	45.0	6	30.0
Community Member	2	1.3	0	0.0
Unidentified			1	5.0
TOTAL	149	100.0	20	100.0

[1] The population consisted of all current Institutional Review Board (IRB) committee members (N = 22) and faculty and students who, as principal investigators, submitted research protocols to the Institutional Review Board for full or expedited review in 1999, 2000, and 2001 (N = 129). There were two committee members who were also included among the list of principal investigators, resulting in an unduplicated N = 149. As the population was identified, University employees were not identified by specific job status and it is only possible to provide subtotal information for this identifier.

Table 2

Affiliation: Population and Survey Respondents

Affiliation	Population		Respondents	
	N	% Total	N	% Total
Center for Psychological Studies	40	26.8	5	25.0
Farquhar Center for Undergraduate Studies	1	0.7	0	0.0
Family Center	1	0.7	0	0.0
Fischler Graduate School of Education and Human Services	15	10.1	4	20.0
Law Center	1	0.7	0	0.0
Oceanographic Center	2	1.3	0	0.0
Huizenga Graduate School of Business and Entrepreneurship	1	0.7	0	0.0
Graduate School of Computer and Information Sciences	1	0.7	0	0.0
Graduate School of Humanities and Social Sciences	12	8.1	1	5.0
Health Professions Division[2]				
College of Allied Health			2	10.0
College of Dental Medicine			2	10.0
College of Medical Sciences			0	0.0
College of Optometry			4	20.0

[2] As the population was identified, it was not possible to discern specific *by college* breakout information for employees associated with the Health Professions Division and it is only possible to provide subtotal information for this identifier.

Affiliation	Population		Respondents	
	N	% Total	N	% Total
College of Osteopathic Medicine			0	0.0
College of Pharmacy			1	5.0
Health Professions Division Subtotal	71	47.7	9	45.0
University Administration	2	1.3	0	0.0
Community Member	2	1.3	0	0.0
Unidentified			1	5.0
TOTAL	149	100.0	20	100.0

Table 3

Responses to Survey Statements: IRB Web Site

Statement	N	Mode	Median	Mean	SD
The IRB Web Site is easy to navigate	18	5	4	3.89	1.23
The information on the IRB Web Site is understandable	18	5	4	4.17	0.99
The information on the IRB Web Site is useful	18	4	4	4.33	0.69
The IRB Web Site provided the information I needed to complete my research protocol	18	5	4	4.22	0.94

Table 4

Responses to Survey Statements: Policy and Procedure Manual for Research with Human Subjects

Statement	N	Mode	Median	Mean	SD
The Manual was understandable	14	4	4	3.50	0.85
The Manual was helpful to me in explaining the IRB process	14	4	4	3.71	0.73
The Manual provided all of the information I needed to complete my research protocol	14	4	4	3.57	1.16

Table 5

Responses to Survey Statements: IRB Forms

Statement	N	Mode	Median	Mean	SD
The IRB Submission Form was understandable	19	4	4	3.95	1.22
The IRB Submission Form was easy to complete	19	5	4	3.84	1.21
The sample research protocols provided on the IRB Web Site were helpful in assisting with the design of my research protocol	17	5	4	3.82	1.29
The sample Informed Consent(s) provided on the IRB Web Site were helpful in assisting with the completion of my Informed Consent(s)	18	5	4	3.83	1.25

Table 6

Responses to Survey Statements: IRB Service and Support

Statement	N	Mode	Median	Mean	SD
OGC staff answered all of my questions regarding the IRB process	16	5	4	4.63	0.81
OGC staff were helpful in assisting me with the completion of my IRB submission	15	5	4	4.47	0.92
OGC staff provided information regarding the status of my research protocol	16	5	4	4.50	0.73
OGC staff were courteous	17	5	4	4.65	0.79
OGC staff responded in a timely manner to my request for information and/or assistance	17	5	4	4.59	0.62
OGC staff displayed knowledge and expertise about the IRB process	17	5	4	4.59	0.62

Table 7

Responses to Survey Statements: Center/College Representative

Statement	N	Mode	Median	Mean	SD
The center representative answered all of my questions regarding the IRB process	17	5	4	3.82	1.55
The center representative provided useful feedback to me about my research protocol	17	3	4	3.65	1.32
The center representative completed a review of my research protocol in a timely manner	17	5	4	3.94	1.43
The center representative displayed knowledge and expertise about the IRB process	17	5	4	3.71	1.31

Table 8

Responses to Survey Statements: Institutional Review Board

Statement	N	Mode	Median	Mean	SD
The IRB fulfills its responsibility to protect human subjects involved in research	19	4	4	4.21	0.71
The IRB reviewed my research protocol in a timely manner	19	4	4	3.68	1.29
The IRB provided constructive feedback on my research protocol	17	4	4	3.47	1.46

NOVA SOUTHEASTERN UNIVERSITY
OFFICE OF GRANTS AND CONTRACTS (OGC)-INSTITUTIONAL REVIEW BOARD (IRB)
CUSTOMER SATISFACTION SURVEY
SEPTEMBER 2001

The purpose of this survey is to elicit information from faculty and student users about Nova Southeastern University's Institutional Review Board process.

Demographic Information

1. Please indicate your job or student status.

- ☐ Dean or associate/assistant dean
- ☐ Academic department chairperson/director
- ☐ Faculty member
- ☐ Student

2. Please check either the academic center in which you are employed or in which you are or were a student.

- ☐ Center for Psychological Studies
- ☐ Farquhar Center for Undergraduate Studies
- ☐ Family Center
- ☐ Fischler Graduate School of Education and Services
- ☐ Law Center
- ☐ Oceanographic Center
- ☐ Huizenga Graduate School of Business and Entrepreneurship
- ☐ Graduate School of Computer and Sciences
- ☐ Graduate School of Humanities and Social Sciences and Social Sciences
- ☐ Health Professions Division
  - ☐ College of Allied Health
  - ☐ College of Dental Medicine
  - ☐ College of Medical Sciences
  - ☐ College of Optometry
  - ☐ College of Osteopathic Medicine
  - ☐ College of Pharmacy

The Office of Grants and Contracts has responsibility for providing a variety of resources to the University's Institutional Review Board for research with human subjects and to faculty and students who are involved in conducting research with human subjects. Resources include such things as the IRB Web Site, the *Policy and Procedure Manual for Research with Human Subjects*, various forms, and service and support.

IRB WEB SITE

3. Please provide your assessment of the usefulness of the IRB Web Site by checking or circling the appropriate response, using the rating key as a guide.

The IRB Web Site is easy to navigate	5	4	3	2	1	NA
The information on the IRB Web Site is understandable	5	4	3	2	1	NA
The information on the IRB Web Site is useful	5	4	3	2	1	NA
The IRB Web Site provided the information I needed to complete my research protocol	5	4	3	2	1	NA

Comments

POLICY AND PROCEDURE MANUAL FOR RESEARCH WITH HUMAN SUBJECTS

4. Please provide your assessment of the *Policy and Procedure Manual for Research with Human Subjects* by checking or circling the appropriate response, using the rating key as a guide.

The Manual was understandable	5	4	3	2	1	NA
The Manual was helpful to me in explaining the IRB process	5	4	3	2	1	NA
The Manual provided all of the information I needed to complete my research protocol	5	4	3	2	1	NA

Comments

IRB FORMS

5. Please provide your assessment of the various IRB forms used in developing and submitting a research protocol by circling the appropriate number using the rating key as a guide.

The IRB Submission Form was understandable	5	4	3	2	1	NA
The IRB Submission Form was easy to complete	5	4	3	2	1	NA
The sample research protocols provided on the IRB Web Site were helpful in assisting with the design of my research protocol	5	4	3	2	1	NA
The sample Informed Consent(s) provided on the IRB Web Site were helpful in assisting with the completion of my Informed Consent(s)	5	4	3	2	1	NA

Comments

Rating Key			
5	Strongly Agree	2	Disagree
4	Agree	1	Strongly Disagree
3	Neutral, Neither Agree Nor Disagree	NA	Not Applicable

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IRB SERVICE AND SUPPORT

6. From your experience working with the Office of Grants and Contracts (OGC), please provide your assessment of the level of service provided by the staff of the Office by checking or circling the appropriate response, using the rating key as a guide.

OGC staff answered all of my questions regarding the IRB process	5 4 3 2 1 NA
OGC staff were helpful in assisting me with the completion of my IRB submission	5 4 3 2 1 NA
OGC staff provided information regarding the status of my research protocol	5 4 3 2 1 NA
OGC staff were courteous	5 4 3 2 1 NA
OGC staff responded in a timely manner to my request for information and/or assistance	5 4 3 2 1 NA
OGC staff displayed knowledge and expertise about the IRB process	5 4 3 2 1 NA

Comments

The membership of NSU's IRB includes a representative from each center/college, whose responsibility it is to review all research protocols involving human subjects for their respective center/college to determine whether they are exempt from review or subject to expedited or full review by the IRB.

Center/College Representative

7. From your experience working with your center/college representative, please provide your assessment of the level of service provided by your representative by checking or circling the appropriate response, using the rating key as a guide.

The center representative answered all of my questions regarding the IRB process	5 4 3 2 1 NA

Rating Key			
5	Strongly Agree	2	Disagree
4	Agree	1	Strongly Disagree
3	Neutral, Neither Agree Nor Disagree	NA	Not Applicable

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The center representative provided useful feedback to me about my research protocol	5 4 3 2 1 NA
The center representative completed a review of my research protocol in a timely manner	5 4 3 2 1 NA
The center representative displayed knowledge and expertise about the IRB process	5 4 3 2 1 NA

Comments

NSU's IRB is firmly committed to adhering to the basic ethical principles underlying the acceptable conduct of research involving human subjects, as set forth in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research.* Please indicate your comments on the extent to which the IRB conforms to these guidelines.

Comments.

Institutional Review Board

8. From your experience, please provide your assessment of the IRB's review of your research protocol by checking or circling the appropriate response, using the rating key as a guide.

The IRB fulfills its responsibility to protect human subjects involved in research	5 4 3 2 1 NA
The IRB reviewed my research protocol in a timely manner	5 4 3 2 1 NA
The IRB provided constructive feedback on my research protocol	5 4 3 2 1 NA

Comments

Rating Key			
5	Strongly Agree	2	Disagree
4	Agree	1	Strongly Disagree
3	Neutral, Neither Agree Nor Disagree	NA	Not Applicable

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General comments and suggestions

Thank You for Your Participation!
Please use either the enclosed envelope or interoffice mail to return this survey to:

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Research and Planning
3301 College Avenue
Fort Lauderdale, Florida 33314
Attention: Claire Spann
Surveys should be returned by September 28, 2001.

September 2001

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